SUMMARY OF SAFETY AND EFFECTIVENESS DATA
FOR A SUPPLEMENTAL PREMARKET APPROVAL APPLICATION

I. GENERAL INFORMATION

Device Generic Name:	Ophthalmic Excimer Laser System
Device Trade Name:	SVS Apex Plus Excimer Laser Workstation, emphasis® "M" discs
Applicant's Name and Address:	Summit Technology, Inc. 21 Hickory Drive Waltham, MA 02154 USA
PMA ApplicationSupplement Number:	P930034/S13
Date of Panel Recommendation:	July 23, 1999
Date of Notice of Approval to Applicant:	October 21, 1999
Expedited Review:	Expedited review was granted on February 11, 1999 based on the potential public health benefit from reducing the number of patients being treated using laser in situ keratomileusis (LASIK) off-label procedures without standardized LASIK training or labeling information for users or potential patients.

The SVS Apex Plus Excimer Laser Workstation was approved on February 7, 1997 for phototherapeutic keratectomy (PTK)(P910067/S1) and for myopic photorefractive keratectomy (PRK) using a 6.0 mm ablation zone in patients 21 years of age or older with myopia 1.5 to 7.0 D and concomitant astigmatism ≤ 1.5 D whose refractive change for the one year prior to the laser treatment is within ± 1.0 D (P930034/S2). On March 11, 1998 (P930034/S9), the indication for the laser, with emphasis® discs M, was expanded to include toric PRK for the reduction or elimination of mild to moderate myopia (-1.00 to <- 6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D), in which the combined attempted correction must be < -6.00 D spherical equivalent at the spectacle plane. On October 21, 1999 (P930034/S12), the indication for the laser, with emphasis® discs (K and L) and axicon, was further expanded to include hyperopic PRK in patients 21 years of age or older, with documentation of a stable manifest refraction (± 0.5 D) over the past year, for the reduction or elimination of mild to moderate hyperopia (+1.5 to +4.0 D) with low astigmatism (<-1.00 D) at the spectacle plane.

The sponsor submitted this supplement to further expand the indication statement. The updated pre-clinical and clinical work to support this expanded indication is provided in this summary. For more information on the data which supported the approved indications, the Summaries of Safety and Effectiveness Data to the respective PMA applications should be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Please identify Docket # 95M-0179 for PTK, #96M-0274 for myopic PRK, #98M-0329 for toric PRK, or #00M-0424 for hyperopic PRK. The summaries can also be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pdf/p930034.pdf.

II. INDICATIONS FOR USE

Laser in situ Keratomileusis (LASIK) procedure using the SVS Apex Plus Excimer Laser Workstation and emphasis® "M" discs is intended for use:

- for the reduction or elimination of myopia ranging from 0.0 to -14.0 diopters (D) with or without astigmatism ranging from -0.5 to -5.0 D;
- in patients who are 18 years of age or older; and
- in patients with documentation of a stable manifest refraction (± 0.5 D over the past year.

III. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

A. Contraindications:

The Apex Plus for Myopic LASIK, and used in conjunction with the emphasis "M" discs for Toric LASIK is contraindicated for the following patients:

- Patients with uncontrolled vascular disease or autoimmune diseases, because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;
- Women who are pregnant or nursing, due to the potential for temporary fluctuation in refraction with pregnancy;
- Patients with signs of keratoconus, since eyes with this condition may have unstable corneas;
- Patients known to have a previous history of keloid formation, because their corneal healing response is less predictable; and
- Patients taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride).

B. Warnings: see the labeling

C. Precautions: see the labeling

IV. DEVICE DESCRIPTION

A. Laser System

The Apex Plus and emphasis® "M" discs M00, M08, and M09 constitute the device that is the subject of this PMA supplement. The treatment of mild to high myopia without astigmatism ("Myopic LASIK") utilizes the Apex Plus. The treatment of mild to high myopia with astigmatism ("Toric LASIK") utilizes the Apex Plus in conjunction with emphasis® "M" discs.

The excimer laser is the same one previously approved for Toric PRK, but with the addition of software version 3.2.1: Aspheric Multizone and Extended Toric.

B. Microkeratome

The LASIK procedure requires the use of a commercially available microkeratome that has been cleared for marketing via premarket notification. The device used in this study consists of an instrument tray which includes the shaper head, an adjustable height suction ring, handle, wrenches and test shaft. The instrument motor, handpiece, disposable blades, power supply with footswitches and power cords, applanation lens set, tonometer, optical zone marker, spatula, stop attachment, and digital thickness gauge are provided as separate components which complete the system.

V. ALTERNATE PRACTICES OR PROCEDURES

Conventional methods for correcting myopia and astigmatism are:

- spectacles;
- contact lenses;
- Automated Lamellar Keratoplasty (ALK);
- Radial Keratotomy (RK); and
- Photorefractive Keratectomy (PRK).

Each alternative has its own advantages and disadvantages. A prospective patient should fully discuss with his/her care provider these alternatives in order to select the correction method that best meets his/her expectation and lifestyle.

VI. MARKETING HISTORY

Since 1995, Summit Technology, Inc. has sold or distributed over 300 Apex Plus systems worldwide. The Summit Excimer Laser System has not been withdrawn from any country or market for reasons of safety or effectiveness.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse reactions associated with LASIK include: loss of best spectacle corrected visual acuity, worsening of patient complaints such as double vision, sensitivity to bright lights, increased difficulty with night vision, fluctuations in vision, increase in intraocular pressure, corneal haze, secondary surgical intervention, corneal infiltrate or ulcer, corneal epithelial defect, corneal edema, problems associated with the flap including a lost, misplaced or misaligned flap, retinal detachment, and retinal vascular accidents.

Please refer to the complete listing of adverse events and complication observed during the clinical study which are presented on pages 12-14 of the clinical study section.

VIII. SUMMARY OF PRECLINICAL STUDIES

Each disc was individually verified with a lensometer. In addition, nonclinical laboratory studies were performed to evaluate the achieved profiles (depth, width, and radius of curvature) in polymethylmethacrylate (PMMA). Sets of M discs were tested in PMMA to verify that their profiles follow an expected linear relationship of curvature (inverse radius) versus diopter.

A hazard analysis was performed to evaluate the effect of the hardware and software modifications for LASIK correction of myopia and astigmatism. The safety or effectiveness of the device was determined to be unaffected by the change.

IX. SUMMARY OF CLINICAL STUDIES

This study of the LASIK procedure using the Summit Apex Plus Laser System was managed by CRS Clinical Research, Inc. of Scottsdale, AZ under the auspices of an Investigational Device Exemption (IDE) G960186. Data for 1,013 eyes treated and followed for 6 months served as the basis of the approval decision. Specifically, safety and effectiveness outcomes at 6 months post-operative were assessed as stability is reached by that time. Supplemental safety and effectiveness information from an additional 672 eyes, also followed for 6 months, were evaluated for confirmation.

A. Study Objectives

The CRS LASIK Study reported here evaluated the safety and effectiveness of the Apex Plus used in conjunction with emphasis "M" discs to treat 0 to -14.0 D of myopia with and without astigmatism of -0.5 to -5.0 D.

B. Study Design

This was a prospective, non-randomized, unmasked, multi-center clinical study where the primary control was the preoperative state of the treated eye (i.e., comparison of pretreatment and post-treatment visual parameters in the same eye).

C. Inclusion and Exclusion Criteria

Study subjects were 18 years or older and must have signed an informed consent form. Enrollment occurred if the subject met all of the following inclusion criteria: undergoing LASIK surgery for the correction of myopia, have bilateral physiologic myopia, had a stable refraction for the last twelve months, have hard lenses discontinued for three weeks and soft lenses discontinued for three days prior to the pre-operative evaluation, and be able to return for scheduled follow-up examinations for six months after surgery.

Subjects not meeting the above inclusion criteria were excluded from the study. In addition, subjects were prohibited from participating if they met any of the following exclusion criteria: anterior segment pathology, residual, recurrent or active ocular disease, previous intraocular or corneal surgery of any kind in the eye to be treated, history of herpes keratitis, or diagnosed with autoimmune disease, systemic connective tissue diseases or atopic syndrome.

D. Study Plan, Patient Assessments, and Efficacy Criteria

Subjects were evaluated pre-operatively, one day post-operatively, and at 1, 3, and 6 months post-treatment. The one-month post-operative visit was designated as optional in the protocol.

Pre-operatively the subjects' medical and ocular histories were recorded. Post-operatively, subjects were questioned about any visual symptoms and their satisfaction with the procedure. Objective measurements included: uncorrected and best corrected visual acuity, manifest and cycloplegic refraction, keratometry, intraocular pressure, corneal topography, clinical assessment of corneal clarity, clinical assessment of anterior chamber, vitreal, retinal and lens status, and assessment of complications or adverse reactions.

Procedure effectiveness was evaluated based on improvement in uncorrected visual acuity, predictability of the treatment, and reduction in astigmatic component. The stability of the procedure was defined in terms of the change in manifest refraction over time, starting one month after treatment.

E. Study Period, Investigational Sites and Demographic Data

1. Study period and Investigational Sites

The CRS LASIK study was conducted under an investigational device exemptions application approved October 1, 1996. This PMA includes eyes treated through January 1, 1998. There were 20 investigational sites.

2. Demographics

Demographic characteristics with respect to patient age, race and sex are shown in Table 1.

Table 1
Demographic Information
(1013 Eyes of 562 Enrolled Subjects)

Category	Classification	n	%
Sex	Female	548	54.1
	Male	465	45.9
Eye	Right	501	49.5
	Left	512	50.5
Race	Caucasian	732	95.6
	Black	4	0.5
	Asian	11	1.4
	Other	19	2.5
	Not Reported	247	24.4
Age (in Years)	Mean	38.8	
	Standard Deviation	9.4	
	Minimum	18.0	
	Maximum	64.0	

F. Data Analysis and Results

Pre-operative Characteristics

Baseline characteristics for all eyes were evaluated as presented in the following tables 2-6:

Table 2 Treatment Type (n=1013)	
Sphere	428
Spherocylinder	585

Table 3 Treatment Group (n=1013)	
<= -7 D	609
> -7 D	404

Table 4 Manifest Refraction Spherical Equivalent (n=1013)			
	Mean	SD	Range
Sphere (n=428)	-6.64	2.99	-1.00 to -14.25
Spherocylinder (n=585)	-5.55	2.78	+1.25 to -12.77

Table 5 UCVA (n=1013)		
	<= -7D	> -7D
20/20 or better	0.0%	0.0%
20/25 to 20/40	0.8%	0.0%
>20/40 to 20/80	5.5%	0.0%
>20/80 to 20/160	3.7%	0.0%
20/200 or worse	89.9%	100.0%

Table 6 BSCVA (n=1013)		
	<= -7D	> -7D
20/20 or better	90.3%	68.8%
20/25 to 20/40	9.7%	29.9%
>20/40 to 20/80	0.0%	1.3%
>20/80 to 20/160	0.0%	0.0%
20/200 or worse	0.0%	0.0%

2. Post-operative Characteristics and Results

   a. Patient Accountability

   Any retreated patient was considered eligible for examination and inclusion in effectiveness analyses until retreatment; after retreatment those eyes were followed separately. All eyes treated are included in the accountability table below (Table 7).

Table 7 - Accountability All Eyes Eligible for Follow-Up		
Category	**3 Month**	**6 Month**
Available for Analysis	85.9% 870/1013	76.7% 777/1013
Discontinued	0.0% 0/1013	0.0% 0/1013
Not Yet Eligible for Interval	0.0% 0/1013	0/0% 0/1013
Previously Reoperated	4.1% 42/1013	8.7% 88/1013
Missed Visit	10.0% 101/1013	14.6% 148/1013
Total Expected	95.9% 971/1013	91.3% 925/1013
% Accountability	89.6% 870/971	84.0% 777/925

b. Effectiveness Outcomes

(1) Stability

Tables 8 and 9 present the mean change in manifest refraction spherical equivalent (MRSE) for all eyes seen at all follow-up exams (1, 3 and 6 months). Based on MRSE data, stability of treatment appears to be reached between 3 and 6 months with those eyes with refractive error of ≤ -7 D reaching stability before those eyes with refractive error of > -7 D.

Table 8 - LASIK: Stability of Manifest Refraction with ± 1.00 D (1 to 3 M)

From 1 to 3 M						
Full Cohort	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1.00 D	494/542	91.0	295/312	95.0	199/230	87.0
Mean Difference	-0.17 D		-0.16 D		-0.17 D	
SD	0.62 D		0.52 D		0.74 D	
95% CI	88.8% to 93.5%		92.0% to 97.1%		82.1% to 90.9%	
Spheres	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1.00 D	202/215	94.0	111/116	96.0	91/99	92.0
Mean Difference	-0.19 D		-0.12 D		-0.27 D	
SD	0.58 D		0.51 D		0.64 D	
95% CI	90.8% to 97.1%		92.0% to 99.4%		86.6% to 97.3%	
Spherocylinders	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1 .00 D	292/327	89.0	184/196	94.0	108/131	82.0
Mean Difference	-0.15 D		-0.18 D		-0.10 D	
SD	0.65 D		0.52 D		0.81 D	
95% CI	85.9% to 92.6%		90.5 to 97.2%		75.9% to 89.0%	

Table 9 - LASIK: Stability of Manifest Refraction with ± 1.00 D (3 to 6 M)

From 3 to 6 M						
Full Cohort	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1.00 D	627/685	92.0	382/408	94.0	245/277	88.0
Mean Difference	0.05 D		0.06 D		0.03 D	
SD	0.67 D		0.58 D		0.79 D	
95% CI	89.4% to 93.6%		91.3% to 96.0%		84.7% to 92.2%	
Spheres	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1.00 D	262/279	94.0	149/154	97.0	113/125	90.0
Mean Difference	0.05 D		0.07 D		0.04 D	
SD	0.63 D		0.50 D		0.76 D	
95% CI	91.1% to 96.7%		94.0% to 99.6%		85.2% to 95.6%	
Spherocylinders	**All Eyes**		**≤7D**		**>7D**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**
MRSE Change ≤1 .00 D	365/406	90.0	233/254	92.0	132/152	87.0
Mean Difference	0.04 D		0.06 D		0.02 D	
SD	0.70 D		0.62 D		0.82 D	
95% CI	87.0% to 92.8%		88.3 to 95.1%		81.5% to 92.2%	

(2) Uncorrected Visual Acuity (UCVA)

Table 10 presents the UCVA at all post-operative intervals (1, 3, and 6 months) among eyes targeted for emmetropia. These improvements in UCVA support the effectiveness of the device.

Table 10
UCVA in Eyes Intended to be Fully Corrected (Plano Target)

UCVA All Eyes	1 Month (n=606)	3 Months (n=754)	6 Months (n=669)
20/20 or better	41.3% (250/606)	42.6% (321/754)	46.9% (314/669)
20/40 or better	86.3% (523/606)	89.1% (672/754)	92.1% (616/669)

(3) Predictability of Manifest Refractive Spherical Equivalent (MRSE)

Predictability of outcome was determined by comparing the intended MRSE with the achieved MRSE at each visit, as shown in Table 11, for all eyes over the full range of treatment, within ± 1.0 D and ± 2.0 D. Furthermore, at six months within ± 0.50 D, the predictability was 61.3 % (457/745).

Table 11
Predictability of Manifest Refraction

Predictability All Eyes	1 Month (n=644)	3 Months (n=860)	6 Months (n=745)
± 1.00 D	81.2% (523/644)	82.0% (705/860)	83.9% (625/745)
± 2.00 D	95.7% (616/644)	96.0% (826/860)	96.2% (717/745)

(4) Vector Analysis

Table 12 lists a summary of the vector analysis results for all eyes undergoing cylinder correction. The ratio of SIRC/IRC (surgically induced refractive correction/intended refractive correction) indicates the ratio of the vector cylinder change induced compared with the targeted amount. A ratio of 1.0 would indicate that the surgical correction exactly matched the targeted correction. Smaller ratios indicate that the cylinder correction was less than planned, and ratios > 1.0 indicate a cylinder overcorrection. The mean ratio of SIRC/IRC was 0.89 ± 0.50 D. The minimum was 0.00 and the maximum 3.00 D. The minimum and maximum numbers occurred in eyes with relatively small IRC's, as would be expected.

Table 12
Vector Analysis for Eyes Undergoing Cylinder Correction
(Excluding Eyes with Intended Refractive Change of < 0.50 D)
Results reported at 6 Months
(n=510)

	Preoperative	Postoperative	IRC	SIRC	SIRC/IRC
Mean	-1.99	-0.56	-1.98	-1.76	0.89
SD	0.86	0.60	0.78	1.15	0.50
Min	-4.75	-5.25	-4.50	-6.00	0.00
Max	-0.50	0.00	-1.00	0.00	3.00

SIRC=Surgically induced refractive vector change
IRC=Intended refractive vector change

Table 13 stratifies the cylinder correction efficacy according to the preoperative cylinder amounts for all eyes undergoing cylinder correction. Small astigmatic errors tend to be overcorrected and large errors tend to be undercorrected.

Table 13
Cylinder Correction Efficacy Stratified by Preoperative Cylinder at 6 Months

	Percent Reduction of Absolute Cylinder (Not a Vector)		Attempted versus Achieved Vector Magnitude Ration (SIRC/IRC)	
Pre-op Cylinder	Mean	SD	Mean	SD
≤ 1.0 D	49.5%	66.2%	101.9%	33.9%
1.1 - 2.0 D	62.9%	40.6%	94.3%	27.6%
2.1 - 3.0 D	72.8%	22.5%	90.5%	23.9%
3.1 - 4.0 D	76.7%	13.4%	86.0%	17.2%
4.1 – 5.0 D	77.3%	18.4%	88.9%	21.9%

c. Safety Outcomes

(1) Loss of Best Spectacle Corrected Visual Acuity (BSCVA)

Table 14 shows loss of more than 2 lines of BSCVA at 1, 3 and 6 month intervals stratified by treatment group.

Table 14

Change in Best Spectacle Corrected Visual Acuity

Loss of > 2 lines All Eyes	1 Month	3 Months	6 Months
All Eyes	3.0% (19/625)	1.4% (12/849)	2.0% 15/751
≤ -7 D	0.9% 3/350	0.8% 4/517	0.9% 4/452
> -7 D	5.8% (16/275)	2.4% (8/332)	3.3% (10/299)

(2) BSCVA of 20/40 or Worse

As shown in Table 15, the percentage of eyes with a baseline visual acuity of 20/20 or better having a BSCVA worse than 20/40 is below the 1% target value for all groups.

Table 15 Best Spectacle Corrected Visual Acuity Worse Than 20/40	
BSCVA Worse than 20/40 All Eyes	**6 Months**
All Eyes	0.4% (3/751)
≤ -7 D	0.2% (1/452)
> -7 D	0.7% (2/299)

(3) Adverse Events and Complications

One thousand and thirteen (1,013) eyes, followed for 6 months, were used for safety analyses. Adverse events and complications were classified as intra-operative and postoperative. Two adverse events occurred that were related to the surgical procedure. They occurred when the cylinder alignment reticle was left in place during the ablation.

Intra-operative complications are presented below in Table 16.

Table 16. LASIK Intra-Operative Complications (n = 1,013)

Damage to Epithelium	8 (0.8%)
Epithelial Defect	11 (1.1%)
Epithelial Defect w/ Thin Flap	1 (0.1%)
Free Cap	6 (0.6%)
Oval Keratectomy	39 (3.8)
Small Flap	2 (0.2%)
Surgery Aborted: Inadequate Flap	2 (0.2%)
Surgery Aborted: Lost Suction	1 (0.1%)
Thin Flap	5 (0.5%)
Total	75/1013 (7.4%)

With regard to post-operative adverse events and complications, persistent staining indicating a corneal epithelial defect occurred in 2.2% (19/867) of eyes at 3 months. Since the database did not allow for specification of staining type (e.g., cap edge versus simple SPK or superficial punctate keratopathy) it is not possible to say whether these eyes truly had a surgical-related complication.

The following adverse events and complications occurred in more than 1.0% of patients at 6 months: undercorrection > 1.0 D (11.9%); overcorrection > 1.0 D (4.2%); BSCVA less than 20/25 when the pre-operative eye was 20/20 or better (3.0%); and loss of 2 or more lines of BSCVA (1.9%).

The following adverse events and complications occurred at a rate of 1% or less at 6 months: increase in intraocular pressure (IOP), flap edema, flap wrinkling, interface epithelium, and induced astigmatism >2.0 D.

The following adverse events and complications did not occur in this clinical study: corneal infiltrate or ulcer, melting of the flap, late onset of haze, retinal detachment, retinal vascular accidents, drooping of the eyelid, double vision, foreign body sensations, anterior stromal reticular haze, and stromal edema.

(4) Changes in Intraocular Pressure (IOP)

Since the post-operative management of LASIK does not involve the prolonged use of steroids, increases in IOP were rare. As shown in Table 17, most eyes experienced a decrease in the measured IOP, due to the distorted applanation readings that result from the change in corneal thickness and contour. At 6 months, no eyes experienced a rise in IOP of > 10 mm Hg. In summary, IOP rises after LASIK were not a safety problem in this series.

Table 17
Change in IOP

All Eyes (mm Hg)	1 Month	3 Months	6 Months
Decrease > 10	1.2%	2.1%	2.6%
Decrease 6 to 10	12.2%	12.8%	11.3%
Decrease 1 to 5	51.8%	52.6%	56.5%
No Change	13.7%	12.4%	8.5%
Increase 1 to 5	19.6%	18.3%	19.6%
Increase 6 to 10	1.5%	1.8%	1.6%
Increase > 10	0.0%	0.0%	0.0%

(5) Subjective Patient Adverse Events

Table 18 lists the responses to questions about patient subjective complaints. They were obtained from a patient questionnaire that was administered pre-operatively and at 3 months post-operatively, as required in the protocol. Additionally, 115 patients were administered the questionnaire at 6 months.

Table 18
Patient Survey

All Eyes	Preoperative		3 Months	
	None/Mild	Marked/ Severe	None/Mild	Marked/ Severe
Glare	61% (595/971)	39% (376/971)	76% (413/543)	24% (130/543)
Halo	68% (657/971)	32% (314/971)	72% (389/541)	28% (151/541)
Visual Fluctuations	75% (724/971)	25% (247/971)	62% (339/543)	38% (204/543)

Severe glare was reported in 6.4% (62/971) of subjects pre-operatively while 1.7% (2/115) of subjects complained of severe glare at 6 months post-operatively. Severe halos were reported in 5.1% (50/971) of subjects pre-operatively while 3.5% (4/115) of subjects complained of severe halos at 6 months post-operatively. Ten percent (97/971) of subjects reported severe fluctuations pre-operatively while 2.6 % (3/115) of subjects complained of severe fluctuations at 6 months post-operatively.

d. Retreatments

Forty eyes were retreated. Retreatments were, in general, successful. Post-operative information was available on 38 of these cases. In 92.1% (35/38) of eyes, the distance UCVA was 20/40 or better at the last visit.

e. Conclusions

The key safety and effectiveness variables are presented for sphere and spherocylindrical corrections of $\leq$ -7.0 D and > -7.0 D in the four tables 19-22.

Table 19. LASIK: 6-Month Post-Operative Results (≤ -7 D) for Spheres

Spheres	0 to <1.00 D	>1.00 to 2.00 D	>2.00 to 3.00 D	>3.00 to 4.00 D	>4.00 to 5.00 D	>5.00 to 6.00 D	>6.00 to 7.00 D	Cum. Total ≤7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	0	7/12 (58.3)	20/21 (95.2)	17/25 (68.0)	26/40 (65.0)	24/35 (68.6)	11/19 (57.9)	105/152 (69.1)
UCVA 20/40 or better*	0	12/12 (100.0)	21/21 (100.0)	24/25 (96.0)	39/40 (97.5)	30/35 (85.7)	19/19 (100.0)	145/152 (95.4)
MRSE ± 0.50 D	0	13/13 (100.0)	17/20 (85.0)	18/27 (66.7)	30/43 (69.8)	26/40 (65.0)	13/22 (59.1)	117/165 (70.9)
MRSE ± 1.00 D	0	13/13 (100.0)	19/20 (95.0)	26/27 (96.3)	39/43 (90.7)	33/40 (82.5)	18/22 (81.8)	148/165 (89.7)
MRSE ± 2.00 D	0	13/13 (100.0)	20/20 (100.0)	27/27 (100.0)	41/43 (95.3)	39/40 (97.5)	22/22 (100.0)	162/165 (98.2)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0	0/13 (0.0)	0/23 (0.0)	0/25 (0.0)	0/43 (0.0)	0/42 (0.0)	0/24 (0.0)	0/170 (0.0)
BSCVA Worse than 20/40	0	0/13 (0.0)	0/23 (0.0)	0/25 (0.0)	0/43 (0.0)	0/42 (0.0)	0/24 (0.0)	0/170 (0.0)
Increase >2 D Cylinder$^{\Psi}$	0	0/13 (0.0)	0/23 (0.0)	0/27 (0.0)	1/45 (2.2)	0/43 (0.0)	0/25 (0.0)	0/176 (0.6)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	0	0/11 (0.0)	0/23 (0.0)	0/25 (0.0)	0/42 (0.0)	1/40 (2.5)	0/22 (0.0)	0/163 (0.6)

*For all eyes minus those intentionally undercorrected.

$^{\Psi}$For eyes treated for spherical corrections only.

Table 20. LASIK: 6-Month Post-Operative Results (≤ -7 D) for Spherocylinders

Spherocylinders	0 to <1.00 D	>1.00 to 2.00 D	>2.00 to 3.00 D	>3.00 to 4.00 D	>4.00 to 5.00 D	>5.00 to 6.00 D	>6.00 to 7.00 D	Cum. Total ≤7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	2/3 (66.7)	13/28 (46.4)	29/53 (54.7)	20/48 (41.7)	21/44 (47.7)	26/52 (50.0)	14/37 (37.8)	125/265 (47.2)
UCVA 20/40 or better*	3/3 (100.0)	26/28 (92.9)	50/53 (94.3)	44/48 (91.7)	42/44 (95.5)	51/52 (98.1)	32/37 (86.5)	248/265 (93.6)
MRSE ± 0.50 D	2/3 (66.7)	18/27 (66.7)	41/52 (78.8)	28/49 (57.1)	39/51 (76.5)	33/55 (60.0)	26/39 (66.7)	187/276 (67.8)
MRSE ± 1.00 D	2/3 (66.7)	24/27 (88.9)	48/52 (92.3)	41/49 (83.7)	45/51 (88.2)	47/55 (85.5)	34/39 (87.2)	241/276 (87.3)
MRSE ± 2.00 D	3/3 (10.00)	27/27 (100.0)	52/52 (100.0)	48/49 (98.0)	50/51 (98.0)	54/55 (98.2)	38/39 (97.4)	272/276 (98.6)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0/3 (0.0)	2/28 (7.1)	0/53 (0.0)	2/49 (4.1)	0/52 (0.0)	0/55 (0.0)	0/42 (0.0)	4/282 (1.4)
BSCVA Worse than 20/40	0/3 (0.0)	1/28 (3.6)	0/53 (0.0)	0/49 (0.0)	0/52 (0.0)	0/55 (0.0)	0/42 (0.0)	1/282 (0.4)
Increase >2 D Cylinder$^{\Psi}$	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	0/2 (0.0)	2/26 (7.7)	0/47 (0.0)	0/43 (0.0)	1/44 (2.3)	0/46 (0.0)	1/30 (3.3)	4/238 (1.7)

*For all eyes minus those intentionally undercorrected.

$^{\Psi}$For eyes treated for spherical corrections only.

Table 21. LASIK: 6-Month Post-Operative Results (> -7 D) for Spheres

Spheres	>7.00 to 8.00 D	>8.00 to 9.00 D	>9.00 to 10.00 D	>10.00 to 11.00 D	>11.000 to 12.00 D	>12.00 to 13.00 D	>13.00 to 14.00 D	Cum. Total >7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	10/27 (37.0)	13/25 (52.0)	7/21 (33.3)	2/14 (14.3)	1/5 (20.0)	2/8 (25.0)	2/5 (40.0)	37/105 (35.2)
UCVA 20/40 or better*	24/27 (88.9)	24/25 (96.0)	20/21 (95.2)	11/14 (78.6)	3/5 (60.0)	8/8 (100.0)	3/5 (60.0)	93/105 (88.6)
MRSE ± 0.50 D	18/35 (51.4)	17/34 (50.0)	10/27 (37.0)	8/18 (44.4)	1/7 (14.3)	4/9 (44.4)	3/8 (37.5)	61/138 (44.2)
MRSE ± 1.00 D	28/35 (80.0)	29/34 (85.3)	22/27 (81.5)	10/18 (55.6)	3/7 (42.9)	9/9 (100.0)	4/8 (50.0)	105/138 (76.1)
MRSE ± 2.00 D	32/35 (91.4)	34/34 (100.0)	26/27 (96.3)	14/18 (77.8)	6/7 (85.7)	9/9 (100.0)	6/8 (75.0)	127/138 (92.0)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	1/35 (2.9)	1/31 (3.2)	0/27 (0.0)	0/18 (0.0)	0/7 (0.0)	0/9 (0.0)	0/8 (0.0)	2/135 (1.5)
BSCVA Worse than 20/40	0/35 (0.0)	0/31 (0.0)	0/27 (0.0)	0/18 (0.0)	0/7 (0.0)	0/9 (0.0)	0/8 (0.0)	0/135 (0.0)
Increase >2 D Cylinder$^{\Psi}$	1/35 (2.9)	1/35 (2.9)	0/27 (0.0)	0/18 (0.0)	0/7 (0.0)	0/9 (0.0)	0/8 (0.0)	2/139 (1.4)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	1/30 (3.3)	1/27 (3.7)	0/22 (0.0)	2/13 (15.4)	1/5 (20.0)	0/6 (0.0)	0/1 (0.0)	5/104 (4.8)

*For all eyes minus those intentionally undercorrected.

$^{\Psi}$For eyes treated for spherical corrections only.

Table 22. LASIK: 6-Month Post-Operative Results (>-7 D) for Spherocylinders

Spherocylinders	>7.00 to 8.00 D	>8.00 to 9.00 D	>9.00 to 10.00 D	>10.00 to 11.00 D	>11.000 to 12.00 D	>12.00 to 13.00 D	>13.00 to 14.00 D	Cum. Total >7.00 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
Efficacy Variables								
UCVA 20/20 or better*	13/42 (31.0)	19/40 (47.5)	6/28 (21.4)	3/17 (17.6)	2/6 (33.3)	4/13 (30.8)	0/1 (0.0)	47/147 (32.0)
UCVA 20/40 or better*	39/42 (92.9)	38/40 (95.0)	24/28 (85.7)	11/17 (64.7)	5/6 (83.3)	12/13 (92.3)	71/1 (100.0)	130/147 (88.4)
MRSE ± 0.50 D	32/50 (64.0)	27/44 (61.4)	14/31 (45.2)	8/16 (50.0)	4/9 (44.4)	5/13 (38.5)	2/3 (66.7)	92/166 (55.4)
MRSE ± 1.00 D	40/50 (80.0)	37/44 (84.1)	23/31 (74.2)	13/16 (81.3)	5/9 (55.6)	10/13 (76.9)	3/3 (100.0)	131/166 (78.9)
MRSE ± 2.00 D	46/50 (92.0)	41/44 (93.2)	31/31 (100.0)	15/16 (93.8)	8/9 (88.9)	12/13 (92.3)	3/3 (100.0)	156/166 (94.0)
Safety Variables								
Loss of ≥ 2 Lines BSCVA	0/50 (0.0)	2/43 (4.7)	1/31 (3.2)	2/16 (12.5)	3/8 (37.5)	0/13 (0.0)	0/3 (0.0)	8/164 (4.9)
BSCVA Worse than 20/40	0/50 (0.0)	0/43 (0.0)	0/31 (0.0)	1/16 (6.3)	1/8 (12.5)	0/13 (0.0)	0/3 (0.0)	2/164 (1.2)
Increase >2 D Cylinder$^{\Psi}$	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
BSCVA Worse than 20/25 if 20/20 or Better Preoperatively	3/30 (10.0)	0/33 (0.0)	2/19 (10.5)	1/6 (16.7)	1/2 (50.0)	1/10 (10.0)	0/2 (0.0)	8/102 (7.8)

*For all eyes minus those intentionally undercorrected.

$^{\Psi}$For eyes treated for spherical corrections only.

f. Device Failures

There were no device failures reported during this study period.

X. CONCLUSIONS DRAWN FROM THE CLINICAL STUDIES

The data in this application support reasonable assurance of the safety and efficacy of this device when used in accordance with the indications for use.

XI. PANEL RECOMMENDATIONS

On July 23, 1999, the Ophthalmic Devices Panel recommended that the premarket approval supplement for the Summit Apex laser for the LASIK procedure in the treatment of myopia with or without astigmatism be considered approvable with conditions. The conditions recommended by the panel were to:

- modify the refractive ranges for approval;
- stratify safety and effectiveness data by 1 diopter increments;
- add cautionary language related to poorer outcomes in higher degrees of myopia and astigmatism;
- add information regarding individual nomogram adjustment;
- add precautionary language that ablation of the corneal stroma to less than 250 microns from the endothelium may result in corneal ectasia;
- add labeling regarding patients having had prior incisional surgery;
- add a precaution that visual performance (i.e., glare and halos) in patients with larger pupils may be worse in conditions where their pupils are dilated; and
- require that pre-operative refraction be stable to within ± 0.5 diopter for one year prior to surgery.

XII. CDRH DECISION

CDRH concurred with the Ophthalmic Devices Panel's recommendation of July 23, 1999, and worked with the company at the September 2, 1999 labeling meeting (and in subsequent facsimiles) to address the labeling concerns raised by the panel. All CDRH and Panel concerns were addressed and CDRH issued an approval order on October 21, 1999.

XIII. APPROVAL SPECIFICATIONS

- Postapproval Requirements and Restrictions: see Approval Order
- Hazards to Health from Use of the Device: see Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling
- Directions for Use: see the labeling